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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/055,788
	Filing Date	January 16, 2002
	First Named Inventor	ZHENG, XIANG YANG
	Group Art Unit	1743
	Examiner Name	WALLENHORST, MAUREEN
Total Number of Pages in This Submission	Attorney Docket Number	LIFE-043

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Documents <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): 1) Petition for Certificate of Correction (2 pgs.) 2) Certificate of Correction (1 pg.) 3) Copy of Claims from Issued Patent (2 pgs.) 4) Copy of Amendment as filed on January 29, 2004 5) Return Postcard
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Signing Attorney/Agent (Reg. No.)	CAROL M. LASALLE (REG. NO. 39,740) BOZICEVIC, FIELD & FRANCIS LLP
Signature	
Date	August 6, 2004

Certificate  
AUG 12 2004  
of Correction

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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.  
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17 AUG 2004



Express Mail No. *EV 462 737 661 US*

<b>PETITION FOR CERTIFICATE OF CORRECTION UNDER 37 C.F.R. § 1.322 FOR PATENT AND TRADEMARK OFFICE ERROR</b>  Address to: Assistant Commissioner for Patents Washington, D.C. 20231	Attorney Docket Number	LIFE-043
	First Named Inventor	Xiang Yang Zheng
	Application Number	10/055,788
	Filing Date	January 16, 2002
	Patent Number	6,746,872 <i>B2</i>
	Issue Date	June 8, 2004
	Title	CONTROL COMPOSITIONS AND METHODS OF USE FOR COAGULATION TESTS

Sir:

Applicants petition under 37 C.F.R. § 1.322 for a Certificate of Correction to correct errors in the claims for the above-identified patent due to Patent and Trademark Office error.

Transmitted herewith for filing is a Certificate of Correction for the above-identified patent. Please make the following corrections to Claims 1, 17, 28, and 35.

In Claim 1, column 21, line 33, please remove the word "and" after the ";;".

In Claim 1, column 21, line 34, please insert a -- ; -- after the word "ions" and before the word "and".

In Claim 1, column 21, line 34, please remove -- ; -- after the word "and".

In Claim 17, column 22, line 19, please replace the word "carboxylato" with the word -- carboxylate --.

In Claim 21, column 22, line 29 please insert a -- , -- after the word "ions" and before the word "hemoglobin".

In Claim 21, column 22, line 31 please insert a -- , -- after the word "ions" and before the word "hemoglobin".

In Claim 28, column 22, line 57, please remove the word "and" after the ";;".

In Claim 28, column 22, line 58, please insert a -- ; -- after the word "solution" and before the word "and".

In Claim 28, column 22, line 61, please insert the word -- said -- after the word "of" and before the word "calcium".


In Claim 35, column 24, line 3 please insert a -- , -- after the word "composition" and before the word "and".

Enclosed is a copy of the Amendment filed on January 29, 2004, showing the correct form of the Claims. Also enclosed, is a copy of the last page of the issued patent showing the incorrect language of the claims that resulted from Patent and Trademark Office error.

It is believed that no fee is due since the error was made by the Patent and Trademark Office. However, the Commissioner is hereby authorized to charge any fees under 37 C.F.R. § 1.20 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: 8/6/04

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17 AUG 2004

**UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION**

PATENT NO. : 6,746,872 *B2*  
DATED : June 8, 2004  
INVENTOR(S) : Xiang Yang Zheng et al.

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

In Claim 1, column 21, line 33, the word "and" after the "," should be removed.

In Claim 1, column 21, line 34, a -- ; -- should be inserted after the word "ions" and before the word "and".

In Claim 1, column 21, line 34, the -- ; -- after the word "and" should be removed.

In Claim 17, column 22, line 19, the word "carboxylato" should be replaced with the word -- carboxylate --.

In Claim 21, column 22, line 29 a -- , -- should be inserted after the word "ions" and before the word "hemoglobin".

In Claim 21, column 22, line 31 a -- , -- should be inserted after the word "ions" and before the word "hemoglobin".

In Claim 28, column 22, line 57, the word "and" should be removed after the ";;".

In Claim 28, column 22, line 58, a -- ; -- should be inserted after the word "solution" and before the word "and".

In Claim 28, column 22, line 61, the word -- said -- should be inserted after the word "of" and before the word "calcium".

In Claim 35, column 24, line 3 a -- , -- should be inserted after the word "composition" and before the word "and".

MAILING ADDRESS OF SENDER:

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PATENT NO: 6,746,872 *B2*

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**17** AUG 2004

of the between day precision evaluation are shown in Table 6.

TABLE 6

	UCSF Between Day Precision		OHSU Between Day Precision	
	Level 1	Level 2	Level 1	Level 2
Mean	1.0	2.7	1.1	3.0
SD	0.092	0.201	0.083	0.226
% CV	9.1	7.4	7.2	7.7

As can be seen from Table 5 and Table 6, the %CV (coefficient of variation) using the control composition for the within run precision test was 5% or less at each investigation site. The %CV for the between day precision test for the control composition was less than 10% at each investigation site.

While the present invention has been described with reference to the specific embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process step or steps, to the objective, spirit and scope of the present invention. All such modifications are intended to be within the scope of the claims appended hereto.

That which is claimed is:

1. A control composition for a coagulation test, comprising:

- (a) plasma aggregatable particles; and
- (b) calcium ions and;
- (c) hemoglobin.

2. The control composition of claim 1, further comprising at least one optical contrast enhancer.

3. The control composition of claim 1, wherein said particles comprise polymeric beads having charged functional groups on surfaces thereof.

4. The control composition of claim 1, wherein said calcium ions comprise a calcium halide.

5. The control composition of claim 1, further comprising plasma.

6. A control composition for a coagulation test, comprising:

- (a) plasma aggregatable particles;
- (b) a solution of calcium ions;
- (c) plasma; and
- (d) hemoglobin.

7. The control composition of claim 6, wherein said solution of calcium ions further comprises an optical contrast enhancer.

8. The control composition of claim 6, wherein said solution of calcium ions further comprises a dissolved dye.

9. The control composition of claim 6, wherein said particles are suspended in a solution comprising an anti-freeze.

10. The control composition of claim 6, wherein said particles comprise polymeric beads having charged functional groups on surfaces thereof.

11. The control composition of claim 10, wherein said polymeric beads comprise polystyrene, and said charged functional groups comprise carboxylate groups.

12. The control composition of claim 10, wherein said polymeric beads contain a dye.

13. A control composition for a coagulation test, comprising:

- (a) a suspension of polymeric beads having charged functional groups on surfaces of said beads;
- (b) a solution of calcium ions;
- (c) citrated plasma; and
- (d) hemoglobin.

14. The control composition of claim 13, wherein said solution of calcium ions includes an optical contrast enhancer.

15. The control composition of claim 13, wherein said solution of calcium ions comprises a calcium halide solution.

16. The control composition of claim 13, wherein said polymeric beads comprise polystyrene.

17. The control composition of claim 13, wherein said charged functional groups comprise carboxylate groups.

18. The control composition of claim 13, wherein said polymeric beads contain a dye.

19. The control composition of claim 13, wherein said suspension of polymeric beads further comprises an anti-freeze.

20. The control composition of claim 13, wherein said solution of calcium ion further comprises a dissolved dye.

21. A method for evaluating a coagulation test, comprising:

- (a) providing a composition including calcium ions hemoglobin and plasma aggregatable particles;
- (b) combining said calcium ions hemoglobin and said particles with plasma to form a control composition; and

35 (c) introducing said control composition and to said coagulation test.

22. The method of 21, further comprising monitoring coagulation of said control composition.

23. The method of claim 22, further comprising determining a coagulation time for said control composition.

24. The method of claim 23, further comprising determining a relationship between said coagulation time of said control composition and a coagulation time of whole blood associated with said plasma in said control composition.

25. The method of claim 24, further comprising determining a relationship between said coagulation time for said control composition, and a coagulation time using a reference test.

26. The method of claim 25, further comprising determining a calibration curve for said coagulation test.

27. The method of claim 21, wherein said coagulation test comprises a prothrombin time test.

28. The method of claim 21, wherein said providing said composition comprises:

- (a) providing a suspension of said particles;
- (b) providing a solution of said calcium ions; and
- (c) providing a hemoglobin solution and
- (d) combining said suspension of said particles, said hemoglobin solution and said solution of calcium ions.

29. The method of claim 28, wherein said particles comprise polymeric beads having charged functional groups on surfaces thereof.

30. The method of claim 21, wherein providing said composition comprises including at least one optical contrast enhancer in said composition.

23

31. A method for evaluating a coagulation test, comprising:

- (a) providing plasma aggregatable particles;
- (b) providing a solution of calcium ions and a solution containing hemoglobin;
- (c) combining said particles with said solution of said calcium ions and said solution containing hemoglobin;
- (d) adding citrated plasma to said combined said particles and said solutions of said calcium ions and hemoglobin to form a control composition; and
- (e) introducing said control composition to a coagulation test.

32. The method of claim 31, further comprising monitoring coagulation of said control composition.

33. The method of claim 32, further comprising determining a coagulation time for said control composition.

34. The method of claim 33, further comprising determining a relationship between said coagulation time of said control composition, and a coagulation time of whole blood associated with said plasma in said control composition.

24

35. The method of claim 34, further comprising determining a relationship between said coagulation time for said control composition and a coagulation time using a reference test.

36. The method of claim 35, further comprising determining a calibration curve for said coagulation test.

37. The method of claim 31, wherein said solution of said calcium ions comprises an aggregation enhancer.

38. The method of claim 37, wherein said aggregation enhancer comprises hemoglobin.

39. The method of claim 31, wherein said particles comprise polymeric beads with charged functional groups on surfaces thereof.

40. The method of claim 31, wherein said solution of said calcium ions comprises a calcium halide solution.

41. The method of claim 31, wherein said providing said particles comprises suspending said particles in an anti-freeze.

42. The method of claim 31, wherein said coagulation test comprises a prothrombin time test.

\* \* \* \* \*



EXPRESS MAIL LABEL NO. **EV333998110US**

<b>AMENDMENT UNDER 37 C.F.R. §1.312</b>  Address to: Mail Stop Issue Fee Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket	LIFE-043
	Confirmation No.	7478
	First Named Inventor	Zheng, Xiang Yang
	Application Number	10/055,788
	Filing Date	January 16, 2002
	Group Art Unit	1743
	Examiner Name	M. Wallenhorst
	Title "CONTROL COMPOSITIONS AND METHODS OF USE FOR COAGULATION TESTS"	

Sir:

This amendment is responsive to the Notice of Allowance and Fees Due dated November 19, 2003.

Prior to issuance of the above-identified patent application, Applicants respectfully request entry of the amendments set forth below. Applicants submit that the amendments raise no new issues of patentability.

## AMENDMENTS

### IN THE CLAIMS

1. (Currently Amended) A control composition for a coagulation test, comprising:
  - (a) plasma aggregatable particles; ~~and~~
  - (b) calcium ions ~~and~~; and
  - (c) hemoglobin.
2. (Original) The control composition of claim 1, further comprising at least one optical contrast enhancer.
3. (Cancelled)
4. (Original) The control composition of claim 1, wherein said particles comprise polymeric beads having charged functional groups on surfaces thereof.
5. (Previously Amended) The control composition of claim 1, wherein said calcium ions comprises a calcium halide.
6. (Original) The control composition of claim 1, further comprising plasma.
7. (Previously Amended) A control composition for a coagulation test, comprising:
  - (a) plasma aggregatable particles;
  - (b) a solution of calcium ions;
  - (c) plasma; and
  - (d) hemoglobin.
8. (Original) The control composition of claim 7, wherein said solution of calcium ions further comprises an optical contrast enhancer.



9. (Original) The control composition of claim 7, wherein said solution of calcium ions further comprises a dissolved dye.

10. (Cancelled)

11. (Original) The control composition of claim 7, wherein said particles are suspended in a solution comprising an antifreeze.

12. (Original) The control composition of claim 7, wherein said particles comprise polymeric beads having charged functional groups on surfaces thereof.

13. (Original) The control composition of claim 12, wherein said polymeric beads comprise polystyrene, and said charged functional groups comprise carboxylate groups.

14. (Original) The control composition of claim 12, wherein said polymeric beads contain a dye.

15. (Cancelled)

16. (Previously Amended) A control composition for a coagulation test, comprising:

- (a) a suspension of polymeric beads having charged functional groups on surfaces of said beads;
- (b) a solution of calcium ions;
- (c) citrated plasma; and
- (d) hemoglobin.

17. (Original) The control composition of claim 16, wherein said solution of calcium ions includes an optical contrast enhancer.

18. (Original) The control composition of claim 16, wherein said solution of calcium ions comprises a calcium halide solution.

19. (Cancelled)

20. (Original) The control composition of claim 16, wherein said polymeric beads comprise polystyrene.

21. (Original) The control composition of claim 16, wherein said charged functional groups comprise carboxylate groups.

22. (Original) The control composition of claim 16, wherein said polymeric beads contain a dye.

23. (Original) The control composition of claim 16, wherein said suspension of polymeric beads further comprises an antifreeze.

24. (Original) The control composition of claim 16, wherein said solution of calcium ion further comprises a dissolved dye.

25. (Previously Amended) A method for evaluating a coagulation test, comprising:

- (a) providing a composition including calcium ions, hemoglobin and plasma aggregatable particles;
- (b) combining said calcium ions, hemoglobin and said particles with plasma to form a control composition; and
- (c) introducing said control composition to said coagulation test.

26. (Original) The method of claim 25, further comprising monitoring coagulation of said control composition.

27. (Original) The method of claim 26, further comprising determining a coagulation time for said control composition.

28. (Original) The method of claim 27, further comprising determining a relationship between said coagulation time of said control composition and a coagulation time of whole blood associated with said plasma in said control composition.

29. (Original) The method of claim 28, further comprising determining a relationship between said coagulation time for said control composition, and a coagulation time using a reference test.

30. (Original) The method of claim 29, further comprising determining a calibration curve for said coagulation test.

31. (Original) The method of claim 25, wherein said coagulation test comprises a prothrombin time test.

32. (Currently Amended) The method of claim 25, wherein said providing said composition comprises:

- (a) providing a suspension of said particles;
- (b) providing a solution of said calcium ions; and
- (c) providing a hemoglobin solution; and
- (d) combining said suspension of said particles, said hemoglobin solution and said solution of said calcium ions.

33. (Original) The method of claim 32, wherein said particles comprise polymeric beads having charged functional groups on surfaces thereof.

34. (Original) The method of claim 25, wherein providing said composition comprises including at least one optical contrast enhancer in said composition.

35. (Previously Amended) A method for evaluating a coagulation test, comprising:

- (a) providing plasma aggregatable particles;
- (b) providing a solution of calcium ions and a solution containing hemoglobin;
- (c) combining said particles with said solution of said calcium ions and said solution containing hemoglobin;
- (d) adding citrated plasma to said combined said particles and said solutions of said calcium ions and hemoglobin to form a control composition; and
- (e) introducing said control composition to a coagulation test.

36. (Previously Amended) The method of claim 35, further comprising monitoring coagulation of said control composition.

37. (Previously Amended) The method of claim 36, further comprising determining a coagulation time for said control composition.

38. (Previously Amended) The method of claim 37, further comprising determining a relationship between said coagulation time of said control composition and a coagulation time of whole blood associated with said plasma in said control composition.

39. (Previously Amended) The method of claim 38, further comprising determining a relationship between said coagulation time for said control composition, and a coagulation time using a reference test.

40. (Original) The method of claim 39, further comprising determining a calibration curve for said coagulation test.

41. (Original) The method of claim 35, wherein said solution of said calcium ions comprises an aggregation enhancer.

42. (Original) The method of claim 41, wherein said aggregation enhancer comprises hemoglobin.

43. (Original) The method of claim 35, wherein said particles comprise polymeric beads with charged functional groups on surfaces thereof.

44. (Original) The method of claim 35, wherein said solution of said calcium ions comprises a calcium halide solution.

45. (Original) The method of claim 35, wherein said providing said particles comprises suspending said particles in an antifreeze.

46. (Original) The method of claim 35, wherein said coagulation test comprises a prothrombin time test.

47.-54. (Cancelled)

**REMARKS**

Claims 1-2, 4-9, 11-14, 16-18, 20-46 remain pending in the application. Claims 3,10, 15, 19 and 47-54 were previously cancelled.

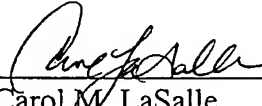
By this Amendment, claims 1 and 32 are being amended to correct typographical errors.

No new subject matter has been added. Accordingly, Applicants respectfully request entry of the Amendment.

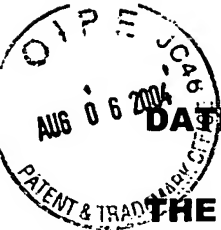
The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number LIFE-043.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: 1/29/4

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DATE: August 6, 2004

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Signature

Date

8/6/04

Atty. Docket No.	Serial Number	Description	Atty.	Fee
AERX-091-	10/251,898	Transmittal, Restriction Election	KYB	
UCAL-062CON2	10/773,795	IDS, SB08A, Copy of EP Communication dated 07/13/04, (1) Cited Reference	KYB	
STAN-290US1	10/794,589	Transmittal, Fee Sheet <i>in duplicate</i> , Copy of Notice to File Missing Parts, Supplemental ADS, Executed Declaration, Seqlist Certification, Paper Copy of Seqlist, (1) CD w/Seqlist in CRF	BEF	\$495
UCAL-135	09/564,710	Transmittal, Petition for Certificate of Correction, Certificate of Correction, Copy of Columns 13-14 of USPN 6,756,039, Copy of Amendment 1.312 as filed 12/02/03	BEF	
TEIK-004	10/080,526	Transmittal, Fee Sheet <i>in duplicate</i> , petition for a Certificate of Correction, Certificate of Correction, (6) Pages from USPN 6,761,900, Copy of Notice of Allowance, Copy of Amendment/Response of 11/26/03	BEF	\$100
UCAL-170CON8	10/146,717	Transmittal, Amendment After Final Rejection	PAB	
UCAL-170CON9	10/229,208	Transmittal, Amendment After Final Rejection	PAB	
BERK-008DIV	10/384,099	Transmittal, Restriction Election	PAB	
TGEN-001	09/471,703	Transmittal, Petition for Certificate of Correction, Certificate of Correction, Copy of Columns 13-14 of USPN 6,762,018, Copy of Amendment 1.111 as filed 07/02/03	EJB	
LIFE-043	10/055,788	Transmittal, Petition for Certificate of Correction, Certificate of Correction, Copy of Columns 21-24, Copy of Amendment as filed 01/29/04	CML	
UCAL-132CON	09/895,963	Petition for Certificate of Correction, Certificate of Correction, Copy of Amendment After Final Rejection, Copy of Columns 23-24	KYB	
STAN-238	10/358,370	Transmittal, Amendment After Final Rejection	PAB	